REMARKS

This application is believed to place it in condition for allowance at the time of the next Official Action.

The claims have been amended to correct a typographic error, i.e., to change “identify data” to “identity data”. This is merely a formal correction and does not affect the pending rejections. Entry of this amendment is therefore appropriate and solicited.

Applicant previously elected Group I, drawn to a method and system of managing batches of immunocompetent cells for deferred use, and species I-A (human cells); II-i (blood sample); III-A (bioelectronic information); and IV-C (implemented in a therapeutic protocol including a step for checking the harmlessness of the lymphocytes before re-injection).

Claims 1, 15-18, 20, 25, 30-33, and 35 were rejected under 35 USC 103(a) as allegedly being obvious over LEFESVRE WO 1999/053030. This rejection is traversed.

Claims 1, 2, 15-18, 20, 21, 25, and 30-35 were rejected under 35 USC 103(a) as allegedly being obvious over LEFESVRE in view of CHA (Physiol. Meas. 1994, …). This rejection is traversed.

Claim 1 was rejected under nonstatutory obviousness-type double patenting in view of claims 1 and 7 of U.S. Patent No. 6,415,201 in view of LEFESVRE.

Double Patenting

Claims 1 and 7 of Patent No. 6,415,201 are directed to collecting for management components of the haematopoietic system for reuse on request from a cell treatment center.

As at least implicitly acknowledged by the Official Action, there is no teaching in the '201 patent of the recited a status-characterization step of collecting information characteristic of the status of health and/or the psychological status of said human or animal subject, said status-characterizing information being obtained by processing measurements made on samples selected from a group consisting of blood, fluid, secretions, hair and combinations thereof from said human or animal subject, said status-characterizing information yielding a subject status characterization result indicating the status of health status and/or the psychological status of said subject for a personal cell library containing a sum of immunity information stored in the membranes of the collected immunocompetent cells.

Nor does the '201 patent teach the recited performing an identification of the batches of cells by consulting said cell management database, and receiving from said cell management database said subject's identity data, upon receiving a request concerning said subject from a cell treatment entity, determining a protocol of deferred use for said immunocompetent cells from said identified batches, by processing said subject's identify

data received from said cell management database, and extracting selected ones of said immunocompetent cells from said personal cell library, according to said determined deferred-use protocol, in view of re-using said selected cells into said subject.

Thus, the obviousness type double patenting issue is based on these missing features being render obvious in view of LEFESVRE. Applicants maintain that LEFESVRE (alone or with CHA) does not render obvious these features, as discussed below with respect to the two pending obviousness rejections.

Claim 1

With respect to claim 1, LEFESVRE teaches managing batches of immunocompetent cells for deferred use including:

-storing batches of cells in cryogenic sites for reuse,

- constituting a personal library of cells with a management database,

- interrogating the database to localize one batch of cell for reuse, and

- transferring the localize batch from the storage site to a requesting cell treatment center.

However, claim 1 also requires "- E) determining a protocol of deferred use for said immunocompetent cells from said identified batches, by processing said subject's identity data received from said cell management database,".

Claim 1 recites the subject's identity data as being derived from a status-characterization step of collecting

information characteristic of the status of the subject's health and/or the psychological status by processing measurements made on samples, the status-characterizing information yielding a subject status characterization result indicating the status of health status and/or the psychological status of said subject.

Claim 1 recites that this status-characterization step includes constituting from the collected cells, a personal cell library of immunocompetent cells containing a sum of immunity information stored in the membranes of the collected immunocompetent cells for determining the subject's identity data including immunity-related data, historical and clinical data on previous diseases, treatments and therapeutic protocols experienced by said subject.

These aspect of the invention are not taught or suggested by LEFESVRE.

Rather, LEFESVRE deals with the constitution and management of batches of cells in order to reuse the cells.

A comparison between Figure 1 of LEFESVRE and the present application will be instructive.

Figure 1 of LEFESVRE (and the Abstract) discloses "***gathering data relating to batches of frozen and stored cell***", which data constitutes a "***database***" used for the "***management of the lymphocytes and monocytes***" and for the "**determination of a batch and location**".

Figure 1 of the present application shows "***cell-batch data gathering***" constituting a "***database cell management***" used for "***cell batch identification***".

Additionally, Figure 1 of the present application shows use of an expert system for re-use protocol determination by processing status-characterizing information.

These concepts are not in LEFESVRE. That is, LEFESVRE does not teach determining a protocol of deferred use for immunocompetent cells from identified batches, by processing said subject's identity data received from a cell management database. LEFESVRE does not teach deriving the subject's identity data by collecting information characteristic of the status of the subject's health and/or the psychological status by processing measurements made on cell samples. LEFESVRE does not teach constituting from the collected cells, a personal cell library of immunocompetent cells containing a sum of immunity information stored in the membranes of the collected immunocompetent cells for determining the subject's identity data including immunity-related data, historical and clinical data on previous diseases, treatments and therapeutic protocols experienced by said subject.

LEFESVRE only teaches that "personal data" collected on the patient is used for "studies and statistical results" whereas the present invention uses "status-characterizing information" gather and process from the collected cells to obtain subject "identity data".

LEFESVRE does not teach gathering status-characterizing information, recited as "said status-characterizing information being obtained by processing measurements made on [the subject's] samples …, said status-characterizing information yielding a subject status characterization result indicating the status of health status and/or the psychological status of said subject".

LEFESVRE does not teach processing status-characterizing information to obtain identity data, recited as "processing said status-characterizing information … for determining the subject's identity data … including immunity-related data, historical and clinical data on previous diseases, treatments and therapeutic protocols experienced by said subject,".

LEFESVRE does not teach inputting such identity data into a database/expert system, recited as "storing the subject's identity data … into a cell management database, [and] performing an identification of the batches of cells by consulting said cell management database, and receiving from said cell management database said subject's identity data, upon receiving a request concerning said subject from a cell treatment entity,".

LEFESVRE does not teach determining a re-use protocol, recited as "determining a protocol of deferred use for said immunocompetent cells from said identified batches, by processing said subject's identity data received from said cell management database".

The present specification teaches that the step e) re-use function avoids immunity problems (page 3, lines 13-20). Linking the re-use of immunocopetent cells to the identity data avoids danger of indiscriminate cell reuse found in the prior art. Indeed, LEFESVRE teaches away from the invention in that LEFESVRE teaches that the re-use of immunocompetent cells are without danger (page 5, lines 2-7 of LEFESVRE WO 99/053030 A1, published in French) reads in French “Ce procédé n’est pas invasif. Il n’introduit pas de cellules étrangères dans l’organisme puisqu’il s’agit de cellules autologues. Il n’y a donc pas à craindre de phénomène de rejet, les systèmes HLA étant compatibles. The translation of this passage is: “This process is not invasive. It doesn’t introduce foreign cells in the body because the cells are autologous cells. There is no risk of rejection phenomenon, the HLA systems being compatible.”

This difference clearly indicate that LEFESVRE does not render obvious the present invention.

CHA is only offered for teaching obtaining bioelectronic information in previously collected blood samples.

All the rejection argues is that it would have been obvious to collect bioelectronic information. There is no teaching as to what purpose such information might be used. Without a suggestion to obtain and use the recited information in the manner of claim 1, the invention is non-obvious.

Independent claims 30, 31, 32, 33, and 35 all include recitations similar to those discussed with respect to claim 1. For the same reasons as discussed with respect to claim 1, these claims are also non-obvious.

In view of the foregoing Remarks, therefore, applicant believes that the present application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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